K090688

510(k) Summary

COOK Biotech Incorporated

JUL 10 2009

COOK® Urological Graft

Manufacturer Name: COOK Biotech Incorporated
1425 Innovation Place
West Lafayette, Indiana 47906
Telephone: +1 (765) 497-3355
FAX: +1 (765) 807-7709

Official Contact: Perry W. Guinn

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: COOK® Urological Graft
Common Name: Surgical Mesh
Classification Regulations: Class II, 21 CFR §878.3300 PAG

INTENDED USE:

The COOK® Urological Graft is for implantation to reinforce soft tissues where weakness exists in the urological anatomy, including temporary wound or solid organ support in the kidney. The Urological Graft is supplied sterile and intended for one-time use.

DEVICE DESCRIPTION:

The COOK® Urological Graft is a bioabsorbable, extracellular collagen matrix that is identical to the predicates SURGISIS® Mesh (K980431) and SURGISIS® Sling (K992159), also manufactured by COOK Biotech Incorporated, and to Vicryl Mesh bag (K051701), manufactured by Ethicon. The device is manufactured from porcine small intestinal submucosa (SIS), packaged in a lyophilized (dried) state and supplied sterile in a sealed double pouch system.

EQUIVALENCE TO MARKETED DEVICES

The COOK Urological Graft is similar with respect to intended use, and identical with respect to materials and technological characteristics to the predicate devices in terms of section 510(k) substantial equivalence, as shown through bench, animal, biocompatibility and clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cook Biotech, Inc.
% Mary A. Faderan, Ph.D., RAC
Regulatory Specialist
1425 Innovation Place
WEST LAFAYETTE IN 47906

SEP 28 2012

Re: K090688
Trade/Device Name: COOK Urological Graft
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: PAG
Dated: July 1, 2009
Received: July 2, 2009

Dear Dr. Faderan:

This letter corrects our substantially equivalent letter of July 10, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

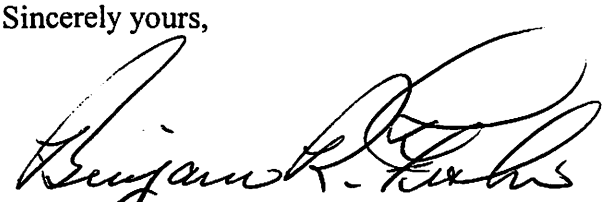
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K090688

Indications for Use

510(k) Number (if known): K090688

Device Name: COOK Urological Graft

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090688